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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,825	01/13/2004	Yi Lu	ILL05-041-US	3704

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EXAMINER

PANDE, SUCHIRA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,825

Applicant(s)

LU ET AL.

Examiner

Suchira Pande

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9-22 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20060907</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/06</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I invention claims 1-8 and 17-25 in the reply filed on September 14, 2006 is acknowledged. The restriction was required between Product and Process. The traversal is on the ground(s) that the elected product is not distinct from the process. This is not found persuasive because Examiner has demonstrated that the inventions were properly shown to be distinct. Two-way distinctness is not required to show distinctness between product and process claims. There is a burden of search requirement, which has been properly explained. The requirement is still deemed proper and is therefore made FINAL.

Applicant has cancelled claims 6-8, 23-25 and 39-41. Claims 1-5, 9-22 and 26-38 are currently pending. Claims 9-16 and 26-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group II invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 14, 2006. Claims 1-5 and 17-22 are being examined in this application.

This application contains claims 9-16 and 26-38 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et. al. (US Pat. 6,890,719 filed on May 10, 2002) in view of Mirkin et. al. (US Pat. 6,361,944 issued Mar. 26, 2002) and Lu et. al. (WO 2004/081235 filed 7 March 2003) .

Regarding claims 1 and 17 Lu et. al. teaches: A sensor system for detecting an effector or cofactor (see col. 9, lines 66-col. 10 lines 1-2 where sensor system to detect an effector or cofactor—metal ions is taught), comprising:

(a) a nucleic acid enzyme, comprising a cofactor binding site and optionally an effector binding site (See col. 10. lines 39-42 where deoxyribozyme, comprising a Pb^{+} binding site is taught);

(b) substrates for the nucleic acid enzyme, comprising first polynucleotides (see col. 9. lines 14-16 where substrate for the (trans-acting) nucleic acid enzyme, comprising first polynucleotides is taught);

Regarding claims 1 and 17 Lu et. al. does not teach: (c) a first set of particles comprising second polynucleotides, wherein polynucleotides are attached to the particles at the 3' terminus; and

(d) a second set of particles comprising third polynucleotides, wherein the polynucleotides are attached to the particles at the 5' terminus; wherein the first polynucleotides comprise or are at least partially complementary to the second polynucleotides, and the first polynucleotides comprise or are at least partially complementary the third polynucleotides.

Regarding claims 2 and 19, Lu et. al. teaches, wherein the nucleic acid enzyme comprises DNA (See col. 10. lines 39-42 where deoxyribozyme, comprising a Pb^{+} binding site is taught).

Regarding claims 5 and 22, Lu et. al. teaches wherein the effector or cofactor is selected from the group consisting of nitrogen fertilizers, pesticides, dioxin, phenols,

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2,4-dichlorophenoxyacetic acid, Pb(II), Hg(II), As(III), UO₂(II), Fe(III), Zn(II), Cu(II), Co(II), glucose, insulin, hCG-hormone, HIV, HIV proteins, anthrax, small pox, nerve gases, TNT, DNT, cocaine and antibiotics. (see col. 10, line 2 where Pb(II) and Hg(II) are taught)

Regarding claims 1 and 17, Mirkin et. al. teaches:

(c) a first set of particles comprising second polynucleotides, wherein polynucleotides are attached to the particles at the 3' terminus(See Fig 16 B oligo labeled 2 wherein polynucleotides are attached to the particles at the 3' terminus through the thiol bond shown by S; and

(d) a second set of particles comprising third polynucleotides, wherein the polynucleotides are attached to the particles at the 5' terminus (See Fig 16 B oligo labeled 1 wherein polynucleotides are attached to the particles at the 3' terminus through the thiol bond shown by S);

wherein the first polynucleotides comprise or are at least partially complementary to the second polynucleotides, and the first polynucleotides comprise or are at least partially complementary the third polynucleotides (See Fig. 16 B where the 3' half of first polynucleotide top strand is complementary to second polynucleotides, wherein polynucleotides are attached to the particles at the 3' terminus through the thiol bond shown by S. The 5' half of first polynucleotide top strand is complementary to second polynucleotides, wherein polynucleotides are attached to the particles at the 5' terminus through the thiol bond shown by S. Also see col. 16 lines 29-40 where nanoparticles

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that can be linked to these the second and third polynucleotides of the invention are described. Also see Fig. 17 A-E and col. 15, lines 7-15).

Regarding claims 3 and 20, Mirkin et. al. teaches wherein the first set of particles and the second set of particles comprise gold (see col. 16, lines 29-31 where gold nanoparticles are taught).

Regarding claims 4 and 21, Mirkin et. al. teaches wherein the first set of particles and the second set of particles comprise a material selected from the group consisting of metals, semiconductors and latex (see col. 16 lines 31-32 where metal and semiconductors are taught. See col. 6 line 53 where latex is taught).

Regarding claim 17, Mirkin et. al. further teaches the set of particles have a diameter of at least 20 nm. (see col. 16 lines 37-40 where size range from about 5 to about 50 nm is taught thereby diameter of at least 20 nm is taught by Mirkin et. al.).

Regarding claim 18, Mirkin et. al. teaches wherein the second set of particles have a diameter of at least 30 nm (see col. 16 lines 37-40 where size range from about 5 to about 50 nm is taught thereby diameter of at least 30 nm is taught by Mirkin et. al.).

It would have been *prima facie* obvious to one of ordinary skill in the art to practice the sensor of Mirkin et. al. in the sensor of Lu et. al. (US Pat. 6,890,719) at the time of the invention. The motivation to do so is provided both by Lu et. al. (WO 2004/081235) and Mirkin et. al.

The advantages of colorimetric sensors over fluorometric sensors used by Lu et. al are taught by Lu et. al. (WO 2004/081235).

Lu et. al. (WO 2004/081235) point out the disadvantages associated with the use of radioisotopes and flurophores in the nucleic acid biosensors (see WO 2004/081235 page 2, lines 17-27). They go on to state "A powerful alternative to flurophore and radio-isotope detection is colorimetry-----". Colorimetric detection minimizes detection costs and safety concerns, and is well suited for on-site and real-time detection. In a colorimetric cocaine sensor based on aptamers-----". Because the dye has different absorption properties when bound to the aptamer, the presence of cocaine is indicated by a color change. However, finding an appropriate dye for a particular aptamer requires screening large number of dyes. Moreover, the extinction coefficient for organic dyes seldom exceeds $10^6 \text{ L} \cdot \text{mole}^{-1} \cdot \text{cm}^{-1}$, necessitating high dye concentration for simple visual observation. Metallic particles have extinction coefficients three orders of magnitude higher than those of organic dyes-----". For effective detection, they may be used in low concentrations (nanomolar) for use as detection agents with aptamers" (see Lu et. al. WO 2004/081235, page 2 lines 28- page 3 lines 1-7)".

Mirkin et. al. state " Presently preferred for use in detecting nucleic acids are gold nanoparticles. Gold colloidal particles have high extinction coefficients for both the bands that give rise to their beautiful colors. These intense colors change with size, concentration, interparticle distance, and extent of aggregation and shape (geometry) of the aggregates, making these materials particularly attractive for calorimetric assays" (see col. 16, lines 64-col. 17 lines 1-4).

Conclusion

All claims under consideration 1-5 and 17-22 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER
11/9/06